OIPE
JAN 0 3 2006
IAP58
PATENT & TRADEMARK OFFICE

AF
ZLW

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 10

Application Number	09/816,641
Filing Date	March 22, 2001
First Named Inventor	Daniel Jacobs et al.
Art Unit	3743
Examiner Name	Andrea Ragonese
Attorney Docket Number	354661-991130 (2502000-991130)

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
 - ☐ Fee Attached
- ☐ Amendment/Reply
 - ☐ After Final
 - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
 - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
 - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please Identify below):
 Return postcard
 Reply Brief in triplicate

Remarks

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account 07-1896.
A duplicate copy of this sheet is enclosed.

Customer No. 26379

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	DLA Piper Rudnick Gray Cary US LLP		
Signature			
Printed name	Alan A. Limbach		
Date	December 30, 2005	Reg. No.	39,749

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature	Kathleen LaBrie		
Typed or printed name	Kathleen LaBrie	Date	December 30, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

American LegalNet, Inc.
www.USCourtForms.com

OIPE IAP58
JAN 0 3 2006
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/816,641
Applicant	:	Daniel Jacobs et al.
Filed	:	March 22, 2001
TC/A.U.	:	3743
Examiner	:	Andrea Ragonese
Title	:	TISSUE TENSION DISTRIBUTION DEVICE FOR A COMBINED ORBITAL RIM REPAIR AND SUSPENSION VARIATION (as amended)
Docket No.	:	2502000-991130
Customer No.	:	26379

M/S Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to **M/S Appeal Brief – Patents**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 30, 2005.

DLA PIPER RUDNICK GRAY CARY Date: 12/30/05

By: Kathleen LaBrie

Kathleen LaBrie

REPLY BRIEF IN RESPONSE TO EXAMINER'S ANSWER

Sir:

This is a Reply Brief in response to the Examiner's Answer of November 3, 2005, which was in response to an appeal from a Final Office Action dated January 26, 2005, an Advisory Action dated May 3, 2005, and from a Notice of Appeal filed on May 26, 2005. **Three copies of this Reply Brief are enclosed.**

Argument

I. Rejection Under 35 U.S.C. 112

The rejection of claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58 under 35 U.S.C. 112, first paragraph, was withdrawn in the Examiner's Answer.

II. Rejections Under 35 U.S.C. 102 and 103

Rejection of Claims 1-2, 13, 16, 18, 21, 24-26 and 54 Under § 102(b)

Claims 1-2, 13, 16, 18, 21, 24-26 and 54 stand rejected under 35 U.S.C. §102(b) as being anticipated by US Patent 5,352,229 (Goble).

In the Applicants' Appeal Brief, the Applicants established that claim 1 recites a supportive backing that combines at least one through-hole, and at least one attachment point extending from the front side of the backing in a non-orthogonal manner. This claimed combination combines non-orthogonally extending attachment point(s) (for improved tissue penetration and stability, and reduced tissue irritation), with through-hole(s) to secure the backing to tissue or bone (for positioning and/or bone fracture repair). In contrast, Goble discloses an arbor press staple and washer, which includes a flat plate 31 and a plurality of straight spikes 35/36 that extend from the plate 31 in an orthogonal manner so that the direction of the spikes match their movement. Therefore, because Goble does not teach or suggest attachment points extending from the backing in a non-orthogonal manner, the Applicants submitted the rejection of this claim was improper.

On page 9 of the Answer, the Examiner provides a first response to Applicants' arguments: since claim 16 provides a Markush grouping of the attachment points which are an admission of equivalent configurations, and that since erect tines or erect nail-shaped tines are orthogonal arrangements, that there is no patentable distinction between orthogonal versus non-orthogonal arrangements of canted hooks. This argument is traversed on several grounds. First, the Examiner provides no support that the listing in claim 16 necessarily means all structure listed therein are "equivalent structures". Claim 16 recites that the orientation of the attachment

points is selected from one of a plurality of configurations, and there is no implication in this claim or in the disclosure that there cannot be a patentable distinction between listed configurations. Second, the Applicants traverse the Examiner's position that the recitation of erect tines or erect nail-shaped tines in claim 16 defines the non-orthogonal configuration specifically recited in parent claim 1 as "orthogonal". Claim 1 specifically recites that the attachment points extend from the backing in a non-orthogonal manner. The Examiner cannot ignore limitations specifically recited in the parent claim when applying a dependent claim. Stated in another way, a dependent claim cannot broaden the scope of coverage of the parent claim to the point that specific limitations are ignored. Claim 16 is consistent with claim 1, because claim 16 simply requires that the attachment point orientation be one of the following:

> "canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines"

Clearly attachments points that extend in a non-orthogonal manner (as recited in claim 1) can further be one of the following: canted tines, canted hooks, canted arrowheads, canted barbed tipped tines, canted arrowhead tipped tines, canted nail-shaped tines, and cheese grater-like tines (as recited in claim 16). Therefore, the Examiner's reliance on claim 16 is erroneous. Lastly, the Applicants traverse the Examiner's conclusion that there cannot be a patentable distinction between the orthogonal versus the non-orthogonal arrangements. This conclusion specifically ignores the teachings of the present application, which states that the attachment point(s) extend from the front side of the backing in a non-orthogonal manner to ensure tissue penetration and approximation stability, and to reduce tissue irritation after device installation (see specification, page 24, lines 3-16).

On page 10 of the Answer, the Examiner provides a second response to the Applicants' arguments:

> "The attachment point 35 extends from the backing 31 in a non-orthogonal manner, since the sides of the extension to which attachment point 35 is connected; on the contrary, the angle is approximately 45°, which would make

> the 'at least one attachment point 35 extending from front side backing 31 in a non-orthogonal manner.'"

From this language, it appears the Examiner is somehow construing "attachment point" as limited only to the very tip of the spike, and is attached to the backing via an "extension" which would be the elongated body of the spike 35. This interpretation is clearly contrary to the specification and the claims. The Applicants' disclosure (against which the claims are construed) makes explicitly clear that "attachment points" are tines or prongs, and not just the very tip of such tines or prongs (see page 21, lines 5+). More importantly, claim 1 recites that the attachment point extends from the front side of the backing (in an non-orthogonal manner), not from any intermediary element such as an "extension". Therefore, it is respectfully submitted that the Examiner's interpretation of Goble is improper.

It is therefore respectfully submitted that claim 1 (and claims 2, 13, 16, 21, 24-26 and 54 dependent thereon), are not anticipated by Goble.

Rejection of Claims 8, 11-12, 46-47 and 49 Under § 103(a)

Claims 8, 11-12, 46-47 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US 4,548,202 (Duncan).

Claims 8, 11-12, 46-47 and 49 all depend from claim 1, which is considered allowable for the reasons set forth above. The addition of Duncan fails to remedy the deficiencies of Goble identified above.

As argued in the Applicants' Appeal Brief, the prior art references fail to suggest the desirability of making the claimed combination of elements in these dependent claims. The text citations from Duncan relied upon by the Examiner regarding "facilitating healing", "hemostatic compression", and accommodating "varying tissue thicknesses" fail to teach or suggest flexibility, porosity, the use of mesh, net, or lattice, biodegradable/biological materials, or intra-operative shaping as recited in dependent claims 8, 11, 12, 46, 47 and 19. More importantly, one having ordinary skill in the art would not modify the device in Goble to make it flexible, make it

porous, make it out of mesh, net or lattice, or make it for intra-operative shaping as suggested by the Examiner, because the Goble device relies on the rigidity of plate 31 so that threaded pin 24 can spikes 35/36 through the ligament and on the bone surface (Col. 6, lines 46+). A primary reference may not be modified in light of or combined with one or more secondary references where the result would be to render the primary reference inoperable for its intended purpose. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

Other than merely reiterating this rejection on page 10 of the Answer, the Examiner does not address the points made above. Therefore, it is respectfully submitted that it would not have been obvious to modify the Goble device as stated by the Examiner, and that these claims are not rendered obvious.

Rejection of Claims 8, 46-47 and 49 Under § 103(a)

Claims 8, 46-47 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 5,779,706 (Tschakaloff).

Claims 8, 46-47 and 49 depend from claim 1, which is considered allowable for the reasons set forth above. The addition of Tschakaloff fails to remedy the deficiencies of Goble (i.e. the combination of Goble and Tschakaloff fails to teach or suggest the claim limitations of these rejected claims). Additionally, as stated above, it would not have been obvious to modify the Goble device in a manner that would render it inoperative for its intended purpose, which is the necessary result of combining Tschakaloff with Goble.

Other than merely reiterating this rejection on page 10 of the Answer, the Examiner does not address the points made above. Therefore, it is respectfully submitted that it would not have been obvious to modify the Goble device as stated by the Examiner, and that these claims are not rendered obvious.

Rejection of Claims 48 and 50 Under § 103(a)

Claims 48 and 50 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble.

It was noted in the Applicants' Appeal Brief that claims 48 and 50 depend from claim 1, which is considered allowable for the reasons set forth above. Moreover, claims 48 and 50 recite that the supportive backing front and back sides are curved or the back side is concave. The Examiner acknowledges that Goble fails to teach or suggest any such configuration of the backing. Instead, the Examiner premises this rejection on a general conclusion that it was well known to form implant devices in a curved configuration and thus it would have been obvious to so modify the backing. First, deficiencies in the factual basis cannot be supplied by resorting to speculation or unsupported generalities. In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967). Secondly, such reliance on what is allegedly well known fails to establish the requisite motivation for combining it with Goble. Thus, it is improper to rely on the stated general conclusion about allegedly known curved implant device configurations. Moreover, MPEP §2144.03 states that while Examiners may take official notice of facts outside of the record, if the applicant traverses such an assertion, "the examiner should cite a reference in support of his or her position". To the extent the Examiner is taking official notice of curved implant devices, and/or of the motivation to combine, the Applicants have specifically traversed this position, and received no cited references to support such a position in response. The Examiner also premised this rejection on a conclusion that the Applicants have not asserted that this specific configuration provides an advantage, solves a problem or serves a purpose different from a planar backing. To the contrary, page 52, lines 12-13 of the disclosure explicitly states that such devices are well suited for orbital reconstruction and suspensions where curves are desirable to accommodate facial bones.

Other than merely reiterating this rejection on page 11 of the Answer, the Examiner does not address the points made above. Therefore, it is respectfully submitted that it would not have

been obvious to modify the Goble device as stated by the Examiner, and that these claims are not rendered obvious.

Rejection of Claims 55-58 Under § 103(a)

Claims 55-58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 6,110,100 (Talpade).

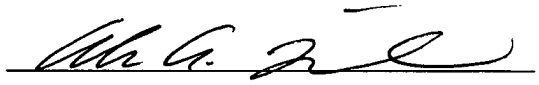
It was noted in the Applicants' Appeal Brief that claims 55-58 depend from claim 1, which is considered allowable for the reasons set forth above. The addition of Talpade fails to remedy the deficiencies of Goble.

Conclusion

For all of these reasons, Applicants respectfully submit that the rejections based upon 35 U.S.C. 102 and 103 are in error and request the Board to affirm the patentability of the claims on appeal.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP

Dated: Dec. 30, 2005 By: 

Alan A. Limbach
Reg. No. 39,749

Attorneys for Applicant(s)

Alan A. Limbach
DLA Piper Rudnick Gray Cary US LLP
2000 University Avenue
East Palo Alto, CA 94303-2248
650-833-2433 (Direct)
650-833-2000 (Main)
650-833-2001 (Facsimile)
alan.limbach@dlapiper.com